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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
ALLEN, MARIANNE P	

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 05/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/930,213	ROSENTHAL ET AL.	
	Examiner	Art Unit	
	Marianne P. Allen	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-27* is/are pending in the application.

4a) Of the above claim(s) *6-8,11 and 15-26* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,9,10,12-14 and 27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I, claims 1-15, in the response submitted 8/18/03 is acknowledged. The traversal is on the ground(s) that there is no burden of search, particularly with respect to Groups I-V. This is not found persuasive because burden of search has previously been established, including the necessity for non-coextensive non-patent literature searches. Applicant has not traversed the election of a particular sequence, in this case SEQ ID NO: 751.

The requirement is still deemed proper and is therefore made FINAL.

Claims 16-26 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the response submitted 8/18/03.

Claims 6-8, 11, and 15 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention. Elected SEQ ID NO: 751 corresponds to the sequence of T119. Claims 6-8, 11, and 15 are not directed to this particular sequence.

All sequences other than SEQ ID NO: 751 are withdrawn from consideration as being drawn to a nonelected invention.

Claims 1-5, 9, 10, 12-14, and newly introduced claim 27 have been examined with respect to SEQ ID NO: 751.

Claim Rejections - 35 USC § 101/112

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-5, 9, 10, 12-14, and 27 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claims are directed to nucleic acids that are products of nature. The nucleic acids are not isolated nor in any way reflect the hand of man.

Claims 1-5, 9, 10, 12-14, and 27 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific, substantial, and credible asserted utility or a well established utility.

SEQ ID NO: 751 is a 255 nucleotide sequence from a rat source. The designation T119 corresponds SEQ ID NO: 751. T119/SEQ ID NO: 751 was found by using subtractive hybridization between phenotypical normal 208 F rat fibroblasts and an H-Ras transformed cell line FE-8 derived from 208 F-cells. Section 2.2 of the specification discloses how the method was performed. T119 is not specifically disclosed as being up-adjusted. Note that it is not present in Figure 7 and Figures 2 and 2A-2E do not appear to identify T119 as a sequence up or down regulated by H-Ras transformation. The description of Figure 11A appears to indicate that T119 is in some way homologous to human sequence SEQ ID NO: 68. SEQ ID NO: 68 is a 402 nucleotide sequence from a human source. However, no alignment or level of homology is disclosed. The specification provides no further discussion concerning SEQ ID NO: 68.

The specification asserts that these nucleic acid sequences can be used for tumor diagnostics or therapeutics. However, there is insufficient information disclosed such that one of

ordinary skill in the art would have been able to use the claimed sequences in this manner in the absence of extensive research and experimentation. At least for example, T119/SEQ ID NO:751 is not associated with any known biological function linked to a known disease process or type of tumor. The necessity for experimentation to determine or reasonably confirm a diagnostic or therapeutic use is not deemed to meet the requirements of a specific, substantial, and credible asserted utility. As such, it is unclear how SEQ ID NO: 751 would be useful in its present form, much less any partial sequence, hybridizing sequence, complementary sequence, or homologous sequence.

Claims 1-5, 9, 10, 12-14, and 27 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific, substantial, and credible asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claims 1-5, 12, and 14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

Claim 1 part (c) is directed in part to a sequence that hybridizes with a sequence of (a) AND (b) under stringent conditions. The specification identifies no sequences meeting these limitations. It is unknown what structure they would possess.

Claim 1 part (d) is directed in part to a sequence that is complementary with a sequence of (a), (b), AND (c). The specification identifies no sequences meeting these limitations. It is unknown what structure they would possess.

All of the nucleic acids embraced by the claims (in view of claim 1 as written) must show a differential expression in tumor cells and normal cells. The specification identifies no partial sequences of SEQ ID NO: 751 having a length of 50, 100, or 200 (for example) that are differentially expressed. The specification identifies no complementary or hybridizing sequences that are differentially expressed. Note that the claimed sequences are not limited to SEQ ID NO: 751. They include naturally occurring sequences from other species, artificial sequences, partial sequences of SEQ ID NO: 751 embedded in other sequences, etc. All of the sequences must be differentially expressed. It is unknown what structure the claimed differentially expressed sequences would have.

Based on the "T" designation it would appear that T119/SEQ ID NO: 751 is not down adjusted. As such, the specification identifies no sequences related to SEQ ID NO: 751 meeting the limitations of claim 5.

The specification identifies no human gene, human cDNA, or partial sequence thereof having the required differential expression. Furthermore, the specification identifies no complete rat gene corresponding to SEQ ID NO: 751. (See claim 14.) It is not known what the structure of such sequences would be.

Claims 1-5, 9, 10, and 12-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-5, 9, 10, 12-14 are indefinite in reciting SEQ ID NOS. or nucleic acid designations (e.g. T103 or N1) that are not under examination.

Claim 1 is confusing in reciting partial sequence lengths that are "preferably" or "especially preferably" at least a certain length. It is unclear whether the claim is intended to be limited to the upper or lower end of the range or some other length.

Claim 9 is confusing in reciting "not yet described as mRNA in rats." It is unclear what limitation this phrase embraces. This claim is interpreted as being directed to a nucleic acid comprising T119 based on the election. Likewise, claim 13 is interpreted as being directed to a nucleic acid comprising T119. As such these claims appear to be duplicative of each other. As T119 corresponds to SEQ ID NO: 751, claims 9 and 13 appear to be duplicative of claim 27 as well. Clarification is requested.

Claim 12 is confusing in reciting "especially human ESTs." It is unclear whether the claim is intended to be limited to human ESTs or EST clusters. Furthermore, it is not clear that this claim further limits claim 1 as no particular level of homology is required.

Claim 14 requires a human gene, a human cDNA, or a partial sequence that corresponds to a rat-homologous gene. It is unknown what structural or functional features define such a correspondence or rat-homologous sequence.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-5, 9, 10, 12-14, and 27 are rejected under 35 U.S.C. 102(a) as being anticipated by Genbank Accession No. AF249673(05 June 2000).

Genbank Accession No. AF249673 discloses a 4632 nucleotide sequence from rat. Nucleotides 774-998 of this sequence match SEQ ID NO: 751 exactly. It is noted that this portion of the sequence is in the identified coding region but is not the complete coding region. The reference does not speak to differential expression in tumor cells and normal cells; however, given that the sequence matches exactly and is from the same animal source it appears that these properties would be inherent. Where the claimed and prior art products are identical or substantially identical in structure or composition, a prima facie case of either anticipation or obviousness has been established. See *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). With respect to claim 14, as no human gene corresponding to a rat-homologous gene has been identified in the specification and absent evidence to the contrary, the reference sequence is considered to represent a human cDNA or a partial sequence thereof. Note that the nucleotides (A, G, C, T) present in DNA from a human source do not differ from those present in DNA from a rat source.

Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne P. Allen whose telephone number is 571-272-0712. The examiner can normally be reached on Monday-Thursday, 5:30 am - 1:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571-272-0722. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Marianne P. Allen
Primary Examiner 5/6/04
Art Unit 1631

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